



Office of Laboratory Quality Assurance
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Notification of Changes in Medical Test Site License

License # MTS-_____ CLIA #:_____ Fax Number _____
Medical Test Site Name _____ Effective Date of Change _____
Signature of Authorized Representative _____

List tests that are being added to your Medical Test Site license and your estimated annual volume

We will need the following information faxed to us before we can process the changes

- Qualifications of Director and Testing Personnel for Moderate and High Complexity Testing (See page 2)
- Evidence of enrollment in Proficiency Testing (PT) for tests that must be covered by PT (see below)

CHEMISTRY

ALT/SGPT
Albumin
Alkaline phosphatase
Amylase
AST/SGOT
Bilirubin, total (or neonatal)
Blood gas pO₂, pCO₂, pH
Calcium, total
Chloride
Cholesterol, total
HDL Cholesterol
Creatine kinase
Creatine kinase isoenzymes
Creatinine
Glucose
Iron, total
LDH
LDH isoenzymes
Magnesium
Potassium
Sodium
Total Protein
Triglycerides
Urea Nitrogen
Uric Acid

TOXICOLOGY

Alcohol, blood
Blood lead
Carbamazepine
Digoxin
Ethosuximide
Gentamicin
Lithium
Phenobarbital
Phenytoin
Primidone
Procainamide (and metabolite)
Quinidine
Tobramycin
Theophylline
Valproic Acid

ENDOCRINOLOGY

Cortisol
Free Thyroxine
Serum Pregnancy (HCG)
(qualitative or quantitative)
T3 Uptake
Triiodothyronine
TSH
Thyroxine

HEMATOLOGY

Cell Identification
Auto or manual WBC diff
Erythrocyte Count (RBC)
Hematocrit (automated)
Hemoglobin
Leukocyte count (WBC)
Platelet Count
Fibrinogen
Partial thromboplastin time
Prothrombin time

IMMUNOHEMATOLOGY

ABO Group
D (Rh typing)
Antibody Detection
Compatibility testing
Antibody Identification

SYPHILIS SEROLOGY

RPR, VDRL, MHA-TP, etc.

IMMUNOLOGY

Alpha-1 antitrypsin
AFP (tumor marker)
Antinuclear antibody
ASO
HIV
Complement C3, C4
HbsAg, Anti-HBc, HBeAg
IgA, IgE, IgG, IgM
Infectious mononucleosis
Rheumatoid factor
Rubella

BACTERIOLOGY,

MYCOLOGY,

PARASITOLOGY

VIROLOGY

MYCOBACTERIOLOGY

Cover the Specialties according to the different types of testing Performed

MODERATE COMPLEXITY TESTING	HIGH COMPLEXITY TESTING
<p><u>Director</u> (check only one)</p> <p>___ 1. Pathologist w/State license</p> <p>___ 2. MD, DO, DPM w/State license + 1 yr directing or supervising non-waived testing; or 20 CMEs in laboratory practice; or lab training during residency equivalent to 20 CMEs</p> <p>___ 3. PhD in science + board certification (ABB, ABMM, ABCC, ABMLI); or 1 yr directing or supervising non-waived testing</p> <p>___ 4. Master in science + 1 yr lab training and/or experience; and 1 yr laboratory supervisory experience</p> <p>___ 5. Bachelor in science + 2 yrs lab training and/or experience; and 2 yrs laboratory supervisory experience</p> <p>___ 6. On 2/28/92, serving as a lab director and qualified or could have qualified as director under previous Medicare/CLIA independent lab personnel requirements</p> <p>___ 7. On 2/28/92, was qualified under State law to direct lab</p>	<p><u>Director</u> (check only one)</p> <p>___ 1. Pathologist w/ State license</p> <p>___ 2. MD, DO, DPM w/State license + 1 yr lab training during medical residency; or 2 yrs directing or supervising high complexity testing</p> <p>___ 3. PhD in science + board certification (ABB, ABMM, ABCC, ABMLI); or until 12/31/2000: 2 yrs lab training and/or experience and 2 yrs directing or supervising high complexity testing</p> <p>___ 4. On 2/28/92, serving as a lab director and qualified or could have qualified as director under previous Medicare/CLIA independent lab personnel requirements</p> <p>___ 5. On 2/28/92, was qualified under State law to direct lab</p> <p>___ 6. For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology (dentists), American Board of Pathology, or American Osteopathic Board of Pathology or equivalent</p>
<p><u>Testing Personnel</u></p> <p>___ 1. MD, DO, DPM, PhD, MS or BS degree in science, or AA degree in science or medical lab technology</p> <p>___ 2. H.S. graduate or equivalent + 50 week military medical laboratory procedures course</p> <p>___ 3. H.S. graduate or equivalent with documented training for testing performed</p>	<p><u>General Supervisor</u></p> <p>___ 1. Pathologist w/State license</p> <p>___ 2. MD, DO, DPM w/State license + 1 yr of training and/or experience in high complexity testing</p> <p>___ 3. PhD, master or bachelor in science + 1 yr training and/or exper. in high complexity testing</p> <p>___ 4. AS/AA in lab science or medical technology + 2 yr training and/or experience in high complexity testing</p> <p>___ 5. Education equivalent to AA degree (60 semester hrs) in lab science + documented lab training program (at least 3 mos); + 2 yr T/or E in high complex. testing</p> <p>___ 6. On 2/28/92, qualified or could have qualified under previous Medicare/CLIA independent lab personnel require.</p> <p>___ 7. On 9/1/92 served as gen supv + on 4/24/95 graduated from med lab clinical training program or 50 week US military pgm + have 2 yrs T/or E in high complex. testing</p> <p>___ 8. On 9/1/92 served as G.S. + high school graduate + 10 yrs T&E in high complex. testing, including 6 yrs supervisory between 9/1/82-9/1/92.</p>
	<p><u>Testing Personnel</u></p> <p>___ 1. MD, DO, DPM w/State license, PhD, master, bachelor or associate degree in science</p> <p>___ 2. 60 semester hrs in science + approved lab training pgm</p> <p>___ 3. On 2/28/92, previously qualified or could have qualified as a technologist under previous Medicare/CLIA independent lab personnel requirements</p> <p>___ 4. On 4/24/95, H.S. graduate performing high complex. testing + completed med lab clinical training program or 50 week US military pgm</p> <p>___ 5. On 4/24/95, H.S. graduate performing high complex. testing + appropriate training</p> <p>___ 6. Until 9/1/97, H.S. graduate or equivalent with documented training for the testing performed (if hired before 1/19/93, no direct on-site supervision if results reviewed by general supervisor within 24 hours)</p> <p>___ 7. For blood gas analysis, qualify under 1, 2, 3, 4, 5, 6; or bachelor in resp. therapy or cardiovascular technology; or associate degree in pulmonary function</p>